

IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF ILLINOIS

UNITED STATES OF AMERICA, and THE	)	
STATES OF ILLINOIS, CALIFORNIA,	)	
FLORIDA, LOUISIANA, MASSACHUSETTS,	)	
MICHIGAN, MONTANA, NEVADA,	)	
NEW JERSEY, NEW MEXICO, NEW YORK,	)	No. <u>1:09-cv-04319</u>
OKLAHOMA, RHODE ISLAND, TENNESSEE,	)	
TEXAS, VIRGINIA, WISCONSIN, <i>ex rel.</i> JOHN	)	Honorable James B. Zagel
STONE, and JOHN STONE individually,	)	
	)	Magistrate Morton Denlow
Plaintiffs,	)	
	)	
v.	)	
	)	<b>JURY TRIAL DEMAND</b>
OMNICARE, INC.	)	
	)	
Defendant.	)	

**PLAINTIFFS' FIRST AMENDED COMPLAINT WITH JURY DEMAND**

John Stone ("Relator") files this action both individually and on behalf of the States of Illinois, California, Florida, Louisiana, Massachusetts, Michigan, Montana, Nevada, New Jersey, New Mexico, New York, Oklahoma, Rhode Island, Tennessee, Texas, Virginia and Wisconsin (collectively referred to as "States"), against Omnicare, Inc. ("Omnicare" or "Defendant") and alleges as follows:

**INTRODUCTION**

1. This is an action for damages and civil penalties on behalf of the United States of America and the States (collectively referenced as "Plaintiffs"), through the Relator, arising from false statements and records made or caused to be made by Defendant to the United States in violation of the False Claims Act, 31 U.S.C. § 3729, *et seq.*, and certain state false claim statutes referenced below. The Defendant's culpable conduct, as alleged with particularity below, includes

presenting false claims to federal and state health care programs for payment for it was not entitled.

### **PARTIES**

2. Defendant is a Delaware corporation with its principal place of business in Covington, Kentucky.

3. Relator is a citizen of the United States and a resident of the State of Kentucky.

4. From November 1, 2004 to May of 2010, Relator was employed by Defendant as the Vice President of Internal Audit.

### **JURISDICTION AND VENUE**

5. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3730 (b). This court has personal jurisdiction over the Defendant pursuant to 31 U.S.C. § 3732(a). This court also has supplemental jurisdiction over Plaintiffs' state law claims under 31 U.S.C. § 3732(b) and 28 U.S.C. § 1367. Venue in this Judicial District is appropriate under 31 U.S.C. § 3732(a) because the Defendant can be found in, and transacts business in, this Judicial District.

6. As a Vice President of Internal Audit for Defendant, Relator has direct, personal, and independent knowledge of the facts underlying the allegations of this Complaint.

7. Relator is the original source of the allegations as defined in 31 U.S.C. § 3730(e)(4)(B). Relator has knowledge of the false statements and/or claims that Defendant submitted, or caused to be submitted, to the Government as alleged herein.

8. Relator brings this action for violations of the False Claims Act ("FCA") on behalf of himself and the United States of America pursuant to 31 U.S.C. § 3730(b)(1).

9. To the extent, if any, that this case is deemed to be a related action and that facts set forth herein are deemed to be the same as facts underlying an existing *qui tam* FCA action pending at the time of filing of this action, as prohibited in 31 U.S.C. § 3730(e)(3), said factual allegations in common with either pending action, which would cause this to be a related cause of action, are hereby expressly excluded from this action, but only to the limited extent necessary to exclude such preemption.

10. Furthermore, to the extent that the court finds that the allegations or transactions set forth herein are based upon allegations or transactions which are the subject of a federal civil suit or an administrative civil money penalty proceeding in which the United States is already a party, if any such proceedings exist, then the allegations or transactions referred to herein that the court deems are based upon allegations or transactions which are the subject of any such civil suit or administrative civil money penalty proceeding are expressly excluded, but only for the specific time periods, specific companies, and specific allegations or transactions as necessary and only for those allegations for which the Court determines Relator is not the original source.

## **I. ANCILLARY SERVICES - MEDICARE**

### **A. Overview**

11. Defendant conducts business in forty-seven (47) states in the United States, the District of Columbia, and Canada.

12. Defendant is the nation's largest provider of pharmaceuticals and related pharmacy and ancillary services to long-term healthcare institutions. Defendant's clients include primarily skilled nursing facilities ("SNFs"), assisted living facilities ("ALFs"), retirement centers, independent living communities, hospices, and other healthcare settings and service providers.

13. With respect to Defendant's ancillary services, Defendant supplies durable medical

equipment including, but not limited to, intravenous medications and nutrition products, respiratory therapy services, and other durable medical equipment and supplies.

14. Defendant generated approximately 100 million dollars in annual revenue in 2008 from its provision of ancillary services, approximately 60 percent of which derived from the Medicare and Medicaid programs.

**B. Medicare**

**i. Requirements for Medicare Reimbursement**

15. At all times relevant herein, four (4) DME Regional Carriers (DMERCs) processed DME claims for Medicare Part B reimbursement. 42 U.S.C. 1395u; 42 C.F.R. 421.210. The DMERCs performed a variety of functions, including making coverage determinations and reimbursing DME suppliers, like Defendant, on the basis of assignment of benefits executed by the Medicare beneficiary. 42 U.S.C. 1395u(b)(3)(B); 42 C.F.R. 421.214, 424.55.

16. Before submitting a claim for Medicare reimbursement, the supplier must have on file:

- a. A dispensing order;
- b. A detailed written order;
- c. A certificate of medical necessity (if applicable);
- d. A DME Information Form (if applicable);
- e. Information from the treating physician concerning the patient's diagnosis; and,
- f. Information required for the use of specific modifiers or attestation statements as defined in certain Durable Medical Equipment Medicare Administrative Contractor ("DME MAC") policies.

CMS Program Integrity Manual, Chapter 5, Section 5.8, CMS Publication #100-08 (2008) ("CMS Manual"); DME MAC Jurisdiction A Supplier Manual, Ch. 9, pp. 9-12 (2003-2005) ("DME

Manual”).

17. If the supplier can not substantiate its claim for payment prior to its claim for payment, the claim is improper. CMS Manual at 5.8; DME Manual at 9-12.

18. Suppliers must retain the above-referenced documents in their files for seven (7) years. CMS Manual at 5.8; DME Manual at 9-12.

**ii. Dispensing/Physician Orders**

19. DME suppliers are required to obtain a signed and dated physician order before dispensing a DME item to a beneficiary. CMS Manual at 5.2.1; DME Manual at 9-7.

20. Suppliers may dispense DME items based on verbal or preliminary written orders, but, in such cases, the supplier must obtain a completed detailed written order before submitting the claim for payment and delivering the item to the beneficiary. CMS Manual at 5.2.2; DME Manual at 9-7.

21. Except for those items requiring a detailed written order prior to delivery, if the supplier does not have a written dispensing order prior to dispensing the DME item, the claim for payment will be deemed improper. CMS Manual at 5.2.2; DME Manual at 9-7.

**iii. Detailed Written Order**

22. Before submitting a claim for payment for any DME item, the supplier must have a detailed written order which has been both signed and dated by the treating physician prior to submitting a claim for payment. CMS Manual at 5.2.3; DME Manual 9-7, 9-8.

23. Detailed written orders may take the form of a photocopy, facsimile image, electronically maintained, or original “pen-and-ink” document. CMS Manual at 5.2.3; DME Manual 9-7.

24. Detailed written orders must contain the beneficiary’s name, the signature of the

treating physician, and clearly state the start date of the order. CMS Manual at 5.2.3; DME Manual 9-7, 9-8.

25. If a supplier does not have a signed and dated detailed written order before it submits a claim for payment, the claim will be denied as not reasonable and necessary. CMS Manual at 5.2.3; DME Manual 9-8.

26. A detailed written order is required prior to delivery of certain DME items, including, but not limited to:

- a. Pressure pads, mattress overlays, mattresses, and beds;
- b. Seat lift mechanisms;
- c. Transcutaneous Electrical Nerve Stimulation (TENS) units;
- d. Power operated vehicles; and,
- e. Power wheelchairs.

CMS Manual at 5.2.3; DME Manual 9-8.

27. If a detailed written order is not completed prior to delivery for these and other items, the item will be denied as not reasonable and necessary. CMS Manual at 5.2.3; DME Manual 9-8.

#### **iv. Evidence of Medical Necessity**

28. For suppliers of durable medical equipment to be eligible for Medicare reimbursement, the beneficiary's physician must certify that the services provided were medically required. 42 U.S.C. 1395n(a)(2); 42 U.S.C. 1395y(a)(1)(A); 42 C.F.R. 411.15(k)(1).

29. For any DME item to be covered by Medicare, the patient's record must contain sufficient documentation of the patient's medical condition to substantiate the necessity for the type and quantity of items ordered and, if applicable, for the frequency of use or replacement. CMS Manual at 5.3; DME Manual at 9-9, 9-10.

30. Depending on the DME item, a Certificate of Medical Necessity (CMN) or DME Information Forms (DIF) must be completed and retained within a patient's record prior to a supplier submitting a claim for payment. CMS Manual at 5.3, 5.8.

31. A CMN is a document containing information showing that an item is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member<sup>1</sup>. CMNs are required for certain DME items, including, but not limited, to:

- a. Oxygen;
- b. Pneumatic Compression Devices;
- c. Osteogenesis Stimulators;
- d. TENS units;
- e. Seat Lift Mechanisms; and,
- f. Section C Continuation Forms.

CMS Manual at 5.3.

32. A DIF is a form completed and signed by the supplier and, unlike CMNs, does not require the cost, a narrative description of equipment, or a physician's signature. DIFs are required for certain DME items, including, but not limited to:

- a. External Infusion Pumps; and,
- b. Enteral and Parenteral Nutrition<sup>2</sup>.

33. In addition to CMNs and DIFs, there must be clinical information in the patient's record which supports the medical necessity for the item and substantiates the dispensing order, CMN, or DIF. CMS Manual at 5.7, 5.8; DME Manual at 9-11.

34. If the patient's record does not adequately support the medical necessity for the item,

---

<sup>1</sup> 42 U.S.C. 1395m(j)(2)(B).

<sup>2</sup> CMS Manual at 5.3.

then the claim for payment is improper. CMS Manual at 5.7, 5.8; DME Manual at 9-9 to 9-12.

**v. Proof of Delivery**

35. Suppliers must maintain proof that the Medicare covered DME item was actually delivered. 42 C.F.R. 424.57(12); CMS Manual at 5.8; DME Manual at 9-12.

36. There are three (3) acceptable methods of delivery:

- a. Supplier delivers directly to the beneficiary or authorized representative;
- b. Supplier utilizes a delivery/shipping service to deliver items; and,
- c. Delivery of items to a nursing facility on behalf of the beneficiary.

CMS Manual at 5.8; DME Manual at 9-12.

37. Medicare reimbursement will be denied for any claims for payment that are not substantiated by proof of delivery. CMS Manual at 5.8; DME Manual at 9-12.

**C. Defendant's Fraudulent Conduct of Submitting False Claims to the Federal Government**

**i. Overview**

38. Since at least 2000, Defendant engaged in the pattern and practice of repeatedly submitting claims to the DMERCs for Medicare reimbursement which could not be substantiated by dispensing orders, detailed written orders, proof of medical necessity, and/or proof of delivery as mandated by Medicare reimbursement rules.

39. Defendant's corporate management created an atmosphere in which its employees feared for their jobs, so they did whatever necessary, legally or not, to collect Medicare and Medicaid reimbursements.

40. As a result of Defendant's fraudulent conduct, the DMERCs unwittingly reimbursed Defendant's claims.

41. By the sheer volume of claims submitted across the United States, Defendant knew,

or should have known, that its claims were false and deficient and that it was not entitled to receive payment.

42. Defendant knowingly distributed DME items to beneficiaries that could not be substantiated as medically unnecessary and submitted claims for federal reimbursement when it could not substantiate that the DME items were actually delivered to a Medicare beneficiary.

**ii. Dispensing/Physician Order**

43. At all times relevant herein, DME suppliers were required to obtain a signed and dated physician order before dispensing any DME items to a beneficiary.

44. Since at least 2000, Defendant repeatedly submitted claims for payment though it did not have a physician's order on file prior to dispensing and billing for the DME item. By way of example, a physician's order did not exist for the following claims for which Defendant was reimbursed by Medicare.

<u>Date of Service</u>	<u>Medicare Reimbursement</u>	<u>Facility</u>
July 1, 2000	\$524.10	OCR of PA
October 23, 2001	\$87.58	Evergreen O2 & SPD <sup>3</sup>
November 3, 2003	\$38.61	Sterling DME <sup>4</sup>
December 7, 2004	\$90.49	Evergreen O2 & SPD
March 29, 2005	\$83.52	Evergreen O2 & SPD
April 1, 2006	Unavailable	OMSS <sup>5</sup>
August 6, 2007	Unavailable	OMSS
January 1, 2008	Unavailable	OMSS

**iii. Proof of Medical Necessity**

45. Since at least 2000, Defendant submitted false, unreimburseable claims for payment to the federal government in that it did not have proof of medical necessity on file prior to dispensing and billing for the DME item. By way of example, proof of medical necessity did not exist for the

---

<sup>3</sup> Evergreen Pharmaceutical.

<sup>4</sup> Sterling Healthcare Services, Inc.

<sup>5</sup> Omnicare Medical Supply Services.

following claims for which Defendant was reimbursed by Medicare:

<u>Date of Service</u>	<u>Medicare Reimbursement</u>	<u>Facility</u>
April 1, 2000	\$336.06	Evergreen O2 & SPD
June 1, 2001	\$264.01	Evergreen O2 & SPD
July 1, 2004	\$190.64	Arlington <sup>6</sup>
August 4, 2004	\$211.82	Arlington
December 1-31, 2004	\$252.86	Arlington
January 1, 2005	\$609.58	Evergreen O2 & SPD
July 26, 2005	\$599.67	Arlington
June 1, 2007	Unavailable	NCP AJ <sup>7</sup>

#### iv. Proof of Delivery

46. According to Section 5.8 of the CMS Manual, Medicare reimbursement will be denied for any claims for payment that are not substantiated by a proof of delivery.

47. Since at least 2000, Defendant submitted false, unreimbursable claims for payment to the federal government in that said claims did not have a proof of delivery on file for the DME items billed to Medicare. By way of example, proof of delivery did not exist for the following claims for which Defendant was reimbursed by Medicare:

<u>Date of Service</u>	<u>Medicare Reimbursement</u>	<u>Facility</u>
March 15, 2000	\$519.70	Evergreen O2 & SPD
March 14, 2001	\$188.90	Sterling IV
January 1, 2004	\$399.17	OCR of PA <sup>8</sup>
March 1, 2004	\$247.46	OCR of PA
May 13, 2005	\$435.06	OCR of PA
August 1, 2005	\$540.14	OCR of PA
September 1, 2005	\$430.16	OCR of PA
September 29, 2007	Unavailable	OMSS

48. In 2009, Defendant attempted to conceal the true scope of the above-described fraudulent practices by remitting a nominal payment to each of the DMERCs. Said payments concealed the true volume of false claims actually submitted to Medicare.

---

<sup>6</sup> Arlington Acquisition I, Inc.

<sup>7</sup> Annapolis Junction.

<sup>8</sup> Omnicare Clinical Research of Pennsylvania.

**D. MEDICAID**

**i. Defendant's Fraudulent Conduct of Submitting False Claims to Various State Medicaid Programs**

49. Defendant wholly owns, operates, and controls facilities which provide ancillary services in the following States:

- a. Arkansas
- b. California
- c. Colorado
- d. Connecticut
- e. Idaho
- f. Illinois
- g. Kentucky
- h. Louisiana
- i. Maine
- j. Massachusetts
- k. Maryland
- l. Michigan
- m. Montana
- n. Nevada
- o. New Jersey
- p. New Mexico
- q. New York
- r. Ohio
- s. Oklahoma

- t. Oregon
- u. Pennsylvania
- v. Rhode Island
- w. Tennessee
- x. Texas
- y. Vermont
- z. Virginia
- aa. Washington
- bb. Wisconsin
- cc. Wyoming

**ii. Representative Medicaid Documentation Policies**

**1. Louisiana Medicaid Program**

50. According to Chapter 18 of the Louisiana Bureau of Health Services Financing Medicaid Services Manual, Section 18.4 (2010) (“Louisiana Manual”), for durable medical equipment, medical necessity must be established for each service and documented, at a minimum, with the following:

- a. Written prescription not more than 12 months old, with the printed name and the dated signature of the recipient’s treating physician or the treating physician’s Advanced Registered Nurse Practitioner (ARNP) or physician assistant. The prescription can be received by the DME and medical supply provider before or after the DME service has been initiated, but the prescription cannot be dated more than 21 days after the initiation of service (date of service);
- b. Current hospital discharge plan with the dated signature of the recipient’s treating physician or the treating physician’s ARNP or physician assistant that clearly describes the type of DME item or service ordered;
- c. Letter of Medical Necessity not more than 12 months old, which includes the printed name and the dated signature of the recipient’s treating physician or the treating physician’s ARNP or physician assistant. Medicaid prohibits vendors from preparing

sections of the letter of medical necessity that are to be completed by the physician or authorized prescriber. The letter of medical necessity cannot be dated more than 21 days after the initiation of service (date of service); or

d. Plan of care, if provider is a home health agency.

51. DME items are covered when medical necessity criteria are met for use as part of the medical care of the recipient. Louisiana Manual at Section 18.1.

52. Delivery documentation must be maintained in the recipient's file and, at a minimum, include the name of the supplier, the beneficiary's full name and 10 digit Medicaid identification number, date of delivery, and dated signature of DME delivery person. Louisiana Manual at Section 18.4.

53. All claims for payment must have a completed prior authorization. The Louisiana Manual provides that if a claim is not authorized prior to the services being rendered, the provider has six (6) months after the date of service to request authorization. If a provider fails to procure prior authorization within 6 months of the date of service, the provider's claim will be denied and it will not receive reimbursement. Louisiana Manual at Section 18.5.

## **2. Illinois Medicaid Program**

54. According to Chapter M-203 of the Illinois Department of Healthcare and Family Services' Policy and Procedures for Medical Equipment and Supplies (2001) ("Illinois Manual"), only those services or items that are reasonably necessary will be covered by Illinois Medicaid.

55. The following documentation must be contained within a patient's record for all claims for payment:

- a. A written physician's order signed and dated by the patient's physician is required for the provision of medical supplies and equipment;
- b. An explanation of the medical necessity for the item or service dispensed, if this is

not included in the physician's order;

- c. Clinical diagnosis, if not included in the physician's order;
- d. Patient's name, recipient identification number (RIN) and address;
- e. A record of items and quantities dispensed and the date(s) dispensed; and,
- f. Approved prior authorization requests, if applicable.

Illinois Manual at M-205.

56. In the absence of the documentation contained in the preceding paragraph, no payment will be made and payments previously made will be recouped. Illinois Manual at M-205.

### **iii. Overview**

57. Since at least 2000, Defendant engaged in the pattern and practice of submitting false, unreimbursable claims for payment to various state health care programs by failing to procure prior to submitting its claim for payment dispensing orders, detailed written orders, proof of medical necessity, prior authorization, and proof of delivery as mandated by state reimbursement rules.

58. As a result of Defendant's fraudulent conduct, various state health care programs unwittingly paid to Defendant and Defendant fraudulent collected from state health care programs reimbursements even though it knew, or should have known, that it was not entitled to receive any payment.

59. In addition to the specific examples provided below, there were numerous claims submitted to state healthcare programs that did not possess any documents, including a physician's order or proof of medical necessity, within the patient's medical file at the time the claim was submitted for payment. For instance, in 2002, Defendant's Sterling Healthcare Services, Inc. (Sterling IV) facility was reimbursed \$13,166.03 by Louisiana Medicaid for claims for which there were no documents contained within the patient's/beneficiary's file at the time the claim was

submitted for reimbursement.

60. As a result of its sheer disregard for the procedural mechanisms established by state health care programs to safeguard against overutilization and in an effort to maximize revenue, Defendant knowingly distributed DME items to beneficiaries that were medically unnecessary and submitted claims for state reimbursement when it could not substantiate that a DME item was actually delivered to a Medicare beneficiary.

#### **iv. Dispensing/Physician Order**

61. At all times relevant herein, DME suppliers were required to obtain a signed and dated physician order before dispensing any DME items to a beneficiary.

62. Since at least 2000, Defendant submitted false, unreimburseable claims for payment to Louisiana Medicaid in that said claims did not have a physician's order on file prior to dispensing and billing for the DME item. By way of example, a physician's order did not exist for the following claims for which Defendant was reimbursed by Louisiana Medicaid:

<u><b>Date of Service</b></u>	<u><b>LA Medicaid Reimbursement</b></u>	<u><b>Facility</b></u>
February 10, 2000	\$9,519.00	Sterling Resp. <sup>9</sup>
January 31, 2001	\$2,160.00	Sterling Resp.
April 8, 2003	\$2,875.20	Sterling Resp.
August 1, 2004	\$424.02	Sterling DME
September 1, 2004	\$688.48	Sterling DME
January 25, 2005	\$146.72	Sterling DME
October 3, 2005	\$1,342.06	Sterling IV <sup>10</sup>
November 5-27, 2005	\$517.20	Sterling IV

63. Since at least 2000, Defendant submitted false, unreimburseable claims for payment to Illinois Medicaid in that said claims did not have a physician's order on file prior to dispensing and billing for the DME item. By way of example, a physician's order did not exist for the following claims for which Defendant was reimbursed by Illinois Medicaid:

---

<sup>9</sup> Sterling Healthcare Services, Inc.

<sup>10</sup> Sterling Healthcare Services, Inc.

<u>Date of Service</u>	<u>IL Medicaid Reimbursement</u>	<u>Facility</u>
October 14, 2003	\$4,212.36	CareTech <sup>11</sup>
November 28, 2003	\$253.84	OIS <sup>12</sup>
April 10, 2004	\$245.86	OIS
July 9, 2004	\$1,278.60	CareTech
October 18, 2004	\$468.43	CareTech
December 21, 2004	\$270.40	CareTech
March 20, 2008	Unavailable	CareTech

64. Relator believes that over Sixty percent (60%) of Defendant's claims for State Medicaid reimbursement were not supported by a physician's order.

**v. Prior Authorization**

65. According to Section 18.5 of the Louisiana Manual, all DME claims submitted for payment must have a prior authorization supporting the item or service within 6 months of the date of service.

66. Since at least 2000, Defendant submitted improper claims for payment to Louisiana Medicaid in that it did not obtain or retain prior authorization for the DME item for which it collected reimbursement. By way of example, prior authorization did not exist for the following claims for which Defendant was reimbursed by Louisiana Medicaid:

<u>Date of Service</u>	<u>LA Medicaid Reimbursement</u>	<u>Facility</u>
March 15, 2000	\$600.00	Sterling Resp.
April 8, 2003	\$2,875.20	Sterling Resp.
May 8, 2003	\$1,920.00	Sterling Resp.
October 11, 2004	\$528.00	Sterling Resp.
January 11, 2005	\$131.40	Sterling Resp.
April 1, 2005	\$320.10	Sterling DME
August 27, 2006	Unavailable	Sterling Resp.

**vi. Proof of Delivery**

67. According to various state health care program manuals, any claim for payment that does not have proof of delivery from the supplier shall be denied.

---

<sup>11</sup> CTLP Acquisition LLC

<sup>12</sup> Oil States International, Inc.

68. Since at least 2000, Defendant submitted improper claims for payment to Louisiana Medicaid in that it did not obtain or retain proof of delivery. By way of example, proof of delivery did not exist for the following claims for which Defendant was reimbursed by Louisiana Medicaid:

<u><b>Date of Service</b></u>	<u><b>LA Medicaid Reimbursement</b></u>	<u><b>Facility</b></u>
August 1, 2000	\$123.82	Sterling DME
May 1, 2001	\$53.15	Sterling DME
July 1, 2003	\$727.88	Sterling DME
March 1, 2004	\$128.81	Sterling DME.
January 25, 2005	\$146.72	Sterling DME
May 1, 2005	\$490.34	Sterling DME
November 28, 2005	\$2,642.36	Sterling IV

69. Since at least 2000, Defendant submitted improper claims for payment to Illinois Medicaid in that it did not obtain or retain proof of delivery. By way of example, proof of delivery did not exist for the following claims for which Defendant was reimbursed by Illinois Medicaid:

<u><b>Date of Service</b></u>	<u><b>IL Medicaid Reimbursement</b></u>	<u><b>Facility</b></u>
October 31, 2003	\$220.77	OIS
November 28, 2003	\$253.84	OIS
October 11, 2004	\$1,265.66	CareTech
November 14, 2004	\$562.81	CareTech
December 7, 2004	\$520.40	CareTech
March 29, 2005	\$615.84	CareTech
July 5, 2005	\$786.38	CareTech

70. Relator believes that over Sixty percent (60%) of Defendant's claims for State Medicaid reimbursement did not contain proof of delivery.

**COUNT 1 – FEDERAL FALSE CLAIMS ACT**  
**31 U.S.C. § 3729(a)(1)**

71. Relator incorporates by reference and re-alleges paragraphs 1-70 as if fully set forth herein.

72. This is an action for damages and civil penalties on behalf of the Government arising from false statements and records made or caused to be made by Defendant to the Government in violation of the FCA, 31 U.S.C. § 3729(a)(1).

73. Defendant knowingly presented, or caused to be presented, false or fraudulent Medicare claims for payment or approval.

74. The Government, unaware of the falsity of the records, statements or Claims made by Defendant, paid Defendant for Claims that would otherwise not have been allowed.

75. By reason of these payments, the Government was and continues to suffer damages in a substantial amount.

76. The Government was unaware of the falsity of the claims made by Defendant through its wholly owned, controlled and operated facilities, and lacking knowledge of the above described fraudulent acts, relied on the accuracy of Defendant's Medicare reimbursement claims to its detriment.

77. In addition to Medicare claims, Defendant submitted claims to various State Medicaid programs which are funded with both state and federal monies. The Federal Government pays a share of the medical assistance expenditures under each State's Medicaid program. That share, known as the Federal Medical Assistance Percentage ("FMAP") or the Federal Financial Participation ("FFP"), is determined annually by a formula that compares the State's average per capita income level with the national income average. States with a higher per capita income level are reimbursed a smaller share of their costs. By law, the FMAP cannot be lower than 50 percent or higher than 83 percent.

78. For each State listed in paragraph 49, the payment by the various States' Medicaid programs on Defendant's false and fraudulent Medicaid claims resulted in the Federal Government paying a FFP which should not have been paid.

COUNT 2 - ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT

79. Relator incorporates by reference and re-alleges Paragraphs 1- 70 as if fully set forth herein.

80. This action is brought by Relator pursuant to the submission of false claims to the State of Illinois in violation of the Illinois Whistleblower Reward and Protection Act, 740 ILL. COMP. STAT. 175/1, et seq.

81. The allegations set forth herein constitute violations of this state's false claims act for which the Relator seeks the maximum award pursuant to the statute.

COUNT 3 - CALIFORNIA FALSE CLAIMS ACT

82. Relator incorporates by reference and re-alleges Paragraphs 1-70 as if fully set forth herein.

83. This action is brought by Relator pursuant to the submission of false claims to the State of California in violation of California False Claims Act, CAL. GOV'T. CODE § 12650, et seq.

84. The allegations set forth herein constitute violations of this state's false claims act for which the Relator seeks the maximum award pursuant to the statute.

COUNT 4 - FLORIDA FALSE CLAIMS ACT

85. Relator incorporates by reference and re-alleges Paragraphs 1- 70 as if fully set forth herein.

86. This action is brought by Relator pursuant to the submission of false claims to the State of Florida in violation of the Florida False Claims Act, FLA. STAT. § 68.081, et seq.

87. The allegations set forth herein constitute violations of this state's false claims act for which the Relator seeks the maximum award pursuant to the statute.

COUNT 5 - LOUISIANA MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW

88. Relator incorporates by reference and re-alleges Paragraphs 1- 70 as if fully set forth herein.

89. This action is brought by Relator pursuant to the submission of false claims to the State of Louisiana in violation of the Louisiana Medical Assistance Programs Integrity Law, LA. REV. STAT. ANN. § 46:437.1, et seq.

90. The allegations set forth herein constitute violations of this state's false claims act for which the Relator seeks the maximum award pursuant to the statute.

COUNT 6 - MASSACHUSETTS FALSE CLAIMS ACT

91. Relator incorporates by reference and re-alleges Paragraphs 1- 70 as if fully set forth herein.

92. This action is brought by Relator pursuant to the submission of false claims to the State of Massachusetts in violation of the Massachusetts False Claims Act, MASS. GEN. LAWS ch.12, § 5A, et seq.

93. The allegations set forth herein constitute violations of this state's false claims act for which the Relator seeks the maximum award pursuant to the statute.

COUNT 7 - MICHIGAN FALSE CLAIMS ACT

94. Relator incorporates by reference and re-alleges Paragraphs 1-70 as if fully set forth herein.

95. This action is brought by Relator pursuant to the submission of false claims to the State of Michigan in violation of the Michigan Medicaid False Claims Act, MICH. COMP. LAWS § 400.601, et seq.

96. The allegations set forth herein constitute violations of this state's false claims act for which the Relator seeks the maximum award pursuant to the statute.

COUNT 8- MONTANA FALSE CLAIMS ACT

97. Relator incorporates by reference and re-alleges Paragraphs 1- 70 as if fully set forth herein.

98. This action is brought by Relator pursuant to the submission of false claims to the State of Montana in violation of the Montana False Claims Act, MONT. CODE. ANN. § 17-8-401, et seq., effective July 1, 2009.

99. The allegations set forth herein constitute violations of this state's false claims act for which the Relator seeks the maximum award pursuant to the statute.

COUNT 9 - NEVADA FALSE CLAIMS ACT

100. Relator incorporates by reference and re-alleges Paragraphs 1- 70 as if fully set forth herein.

101. That in addition to the ancillary services allegations set forth above, Defendant is a purchaser and distributor of the pediatric medication known as Synagis (*Palivizumab-RSV-IgM*).

102. Synagis is an antibody typically prescribed to premature children under the age of two to fight off the respiratory syncytial virus ("RSV"), which can cause serious illness in children. Specifically, the drug is utilized to prevent serious low respiratory tract disease caused by RSV in pediatric patients at high risk of RSV disease.

103. Synagis is supplied as a sterile, preservative-free liquid in solution at 100mg/mL and 50mg/mL vials to be administered by intramuscular injection. Because of the lack of preservative, Synagis must be refrigerated.

104. Synagis' Food and Drug Administration ("FDA") approved label provides: "The single-dose vial of Synagis does not contain a preservative. Administration of Synagis should occur immediately after dose withdrawal from the vial. The vial should not be re-entered. *Discard*

*any unused portion.*” (Emphasis added). Thus, for example, if a prescription orders a dosage of 104mg/mL of Synagis for Patient A, the pharmacy typically orders one 100mg/mL vial and one 50mg/mL vial of Synagis. Synagis’ label requires that the pharmacist then discard the excess 46mg/mL of Synagis to prevent, for example, the risks associated with future off-label distribution or the deterioration of the pharmaceutical.

105. Between the time period of October 2004 to March 2005, Defendant’s facilities engaged in a pattern and practice of submitting false claims to Nevada Medicaid for payments to cover Synagis purchases, which ranged from \$402.05 to \$7,739.10 per vial.

106. Defendant’s facilities engaged in the pattern and practice of not only violating FDA regulations, but also submitting false claims to receive Nevada Medicaid reimbursement in one or more of the following ways:

- a. Defendant intentionally ordered excess Synagis and failed to discard the excess medication as required by Synagis’ FDA approved label;
- b. Defendant’s facilities engaged in the pattern and practice of stockpiling excess Synagis from previous prescriptions and filling new prescriptions with the excess Synagis from previous patients; and,
- c. Defendant’s facilities engaged in the pattern and practice of billing Nevada Medicaid for each Synagis vial prescribed while many, if not most, of the new patients’ prescriptions were being filled with the facility’s stockpiled Synagis excess.

107. Thus, Defendant’s facilities engaged in a pattern and practice of systematically making claims upon the Nevada Medicaid program which were unjustified, unjustifiable, and false.

108. In April of 2006, the Nevada Department of Justice instituted an investigation into Defendant's Arlington Clinical Pharmacy, Inc. (ACP), regarding its inadequate records and incomplete and inaccurate documentation related to Synagis for the time period of November of 2003 to April of 2004.

109. After conducting its investigation, the Nevada Medicaid Fraud Control Unit and Defendant entered into a settlement agreement resolving the following allegations:

- a. During November 2003 through April 2004, ACP routinely submitted claims for reimbursement from Nevada Medicaid concerning the utilization of Synagis. Adequate records were not maintained and/or clearly verifiable in regard to three individual dosages of the drug. ACP's billing department submitted claims for these dosages as if all supporting documentation was complete and accurate;
- b. ACP failed to discover and/or correct the deficiencies and accepted payment for these claims; and,
- c. Allegations of other situations regarding claims submitted for Synagis also existed concerning the time period of November 2003 through April 2004.

110. While the Nevada settlement shed light on Defendant's failure to retain required documentation from November 2003 through April 2004 for claims involving Synagis, the settlement did not address the stockpiling and utilization of excess Synagis to fill new Synagis prescriptions in an effort to maximize Nevada Medicaid reimbursement during the time period of October 2004 to March 2005.

111. This action is brought by Relator pursuant to the submission of false claims to the State of Nevada in violation of the Nevada False Claims Act, NEV. REV. STAT. § 357.010, et seq.

112. The allegations set forth herein constitute violations of this state's false claims act for which the Relator seeks the maximum award pursuant to the statute.

COUNT 10 - NEW JERSEY FALSE CLAIMS ACT

113. Relator incorporates by reference and re-alleges Paragraphs 1- 70 as if fully set forth herein.

114. This action is brought by Relator pursuant to the submission of false claims to the State of New Jersey in violation of the New Jersey False Claims Act, N.J. STAT. ANN. § 2A:32C-1, et seq.

115. The allegations set forth herein constitute violations of this state's false claims act for which the Relator seeks the maximum award pursuant to the statute.

COUNT 11 - NEW MEXICO FRAUD AGAINST TAXPAYERS ACT

116. Relator incorporates by reference and re-alleges Paragraphs 1- 70 as if fully set forth herein.

117. This action is brought by Relator pursuant to the submission of false claims to the State of New Mexico in violation of the New Mexico Fraud Against Taxpayers Act, N.M. STAT. § 27-14-1, et seq.

118. The allegations set forth herein constitute violations of this state's false claims act for which the Relator seeks the maximum award pursuant to the statute.

COUNT 12 - NEW YORK FALSE CLAIMS ACT

119. Relator incorporates by reference and re-alleges Paragraphs 1- 70 as if fully set forth herein.

120. This action is brought by Relator pursuant to the submission of false claims to the State of New York in violation of the New York False Claims Act, N.Y. STATE FIN. LAW, ch.13 § 187, et seq.

121. The allegations set forth herein constitute violations of this state's false claims act for which the Relator seeks the maximum award pursuant to the statute.

COUNT 13 - OKLAHOMA MEDICAID FALSE CLAIMS ACT

122. Relator incorporates by reference and re-alleges Paragraphs 1-70 as if fully set forth herein.

123. This action is brought by Relator pursuant to the submission of false claims to the State of Oklahoma in violation of the Oklahoma Medicaid False Claims Act, OKLA. STAT. TIT. 63, § 5053.1, et seq.

124. The allegations set forth herein constitute violations of this state's false claims act for which the Relator seeks the maximum award pursuant to the statute.

COUNT 14 – RHODE ISLAND FALSE CLAIMS ACT

125. Relators incorporate by reference and re-allege Paragraphs 1-70 as if fully set forth herein.

126. This action is brought by Relators pursuant to the submission of false claims to the State of Rhode Island in violation of the Rhode Island False Claims Act, R.I. GEN LAWS§ 9-1.1-1, et seq.

127. The allegations set forth herein constitute violations of this state's false claims act for which the Relators seek the maximum award pursuant to the statute.

COUNT 15- TENNESSEE MEDICAID FALSE CLAIMS ACT

128. Relator incorporates by reference and re-alleges Paragraphs 1-70 as if fully set forth herein.

129. This action is brought by Relator pursuant to the submission of false claims to the State of Tennessee in violation of the Tennessee Medicaid False Claims Act, TENN. CODE ANN. § 71-5-101, et seq.

130. The allegations set forth herein constitute violations of this state's false claims act for which the Relator seeks the maximum award pursuant to the statute.

COUNT 16 - TEXAS MEDICAID FRAUD PREVENTION ACT

131. Relator incorporates by reference and re-alleges Paragraphs 1-70 as if fully set forth herein.

132. This action is brought by Relator for the State of Texas by reason of the Defendant's commission of unlawful acts in violation of the Texas Medicaid Fraud Prevention Act, TEX. HUM. RES. CODE, ch.36, § 36.001, et seq.

133. The allegations set forth herein constitute violations of this state's Medicaid Fraud Prevention Act, for which the Relator seeks the maximum award pursuant to the statute.

COUNT 17 - STATE OF VIRGINIA FRAUD AGAINST TAXPAYERS ACT

134. Relator incorporates by reference and re-alleges Paragraphs 1-70 as if fully set forth herein.

135. This action is brought by Relator pursuant to the submission of false claims to the State of Virginia in violation of the Virginia Fraud Against Taxpayers Act, VA. CODE ANN. § 8.01-216.1, et seq.

136. The allegations set forth herein constitute violations of this state's false claims act for which the Relator seeks the maximum award pursuant to the statute.

COUNT 18 - STATE OF WISCONSIN FALSE CLAIMS FOR MEDICAL ASSISTANCE ACT

137. Relator incorporates by reference and re-alleges Paragraphs 1-70 as if fully set forth herein.

138. This action is brought by Relator pursuant to the submission of false claims to the State of Wisconsin in violation of the Wisconsin False Claims for Medical Assistance Act, WISC. STAT. § 20.901, et seq.

139. The allegations set forth herein constitute violations of this state's false claims act for which the Relator seeks the maximum award pursuant to the statute.

**II. 31 U.S.C. § 3730(h) RETALIATORY DISCHARGE**

COUNT 19 - FALSE CLAIMS ACT 31 U.S.C. § 3730(h) (Retaliatory Discharge)

140. Relator incorporates by reference all of the above paragraphs as if fully set forth herein.

141. This is an action for damages arising from the illegal discharge of Relator by Defendant in violation of the False Claims Act, 31 U.S.C. § 3729, et seq., as amended.

142. That Section 3730(h) of the FCA states:

Any employee, contractor, or agent shall be entitled to all relief necessary to make that employee, contractor, or agent whole, if that employee, contractor, or agent is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment because of lawful acts done by the employee, contractor, or agent on behalf of the employee, contractor, or agent or associated others in furtherance of other efforts to stop 1 or more violations of this subchapter. Such relief shall include reinstatement with the same seniority status that employee, contractor, or agent would have had but for the discrimination, 2 times the amount of back pay, interest on the back pay, and compensation for any special damages sustained as a result of the discrimination, including litigation costs and reasonable attorneys' fees. An action under this subsection may be brought in the appropriate district court of the United States for the relief provided in this subsection.

143. During 2008, Defendant undertook an internal audit to determine whether its newly acquired pharmacies were in compliance with Medicare and Medicaid statutory and regulatory reimbursement requirements.

144. During November 2008, Relator presented a document to Defendant's Internal Audit committee reflecting the audit deficiencies and stated that said deficiencies resulted in fraud upon Medicare and various State Medicaid programs.

145. As a direct and proximate cause of Relator's presentation to Defendant's Internal Audit Committee, Defendant effectively discharged Relator by telling him to "begin looking for other employment" on or about December 1, 2008<sup>13</sup>.

146. Thus, Relator engaged in protected conduct and Defendant threatened and effectively discharged Relator for lawful actions he took in furtherance of the filing of an action under 31 U.S.C. § 3729.

### **REQUEST FOR TRIAL BY JURY**

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiffs hereby demand trial by jury.

### **PRAYER**

WHEREFORE, Relator prays for judgment against Defendant as follows:

- a. That Defendant be found to have violated and be enjoined from future violations of the Federal False Claims Act and various State False Claims Acts listed herein;
- b. That this Court enter judgment against Defendant for the maximum amount of damages sustained by each State because of Defendant's false or fraudulent claims,

---

<sup>13</sup> The Affidavit of Relator John Stone, previously submitted in support of Relator's Response to Defendant's Motion to Dismiss (Doc. No. 31), paragraph 5, contains the typographical error "December 1, 2009."

plus the maximum civil penalty for each violation of the various State False Claims Acts listed herein;

- c. That this Court enters judgment against Defendant in an amount equal to three times the amount of damages the Federal Government has sustained because of Defendant's false or fraudulent claims. That because Defendant has operated, and is presently operating, under a corporate integrity agreement during most of the period covered by the Amended Complaint allegations, the maximum civil penalty for each violation of 31 U.S.C. § 3729 is particularly warranted;
- d. That Relator be awarded the maximum amount allowed pursuant to § 3730(d).
- e. That with respect to Relator's individual employment claim pursuant to 31 U.S.C. 3730(h), that Defendant immediately reinstate Relator to his former job at the same rate of pay with normal pay increases from the date of discharge to the date of reinstatement, pay Relator two times the amount of back pay, plus interest on the back pay, from the date of discharge to the date of reinstatement, and require Defendant to pay Relator's costs and attorneys fees associated with his individual employment claim in accordance with 31 U.S.C. 3730(h);
- f. That Relator be awarded all costs of this action, including expert witness fees, attorneys' fees, and court costs; and,
- g. That Relator recovers such other relief as the Court deems just and proper.

Respectfully Submitted,

/s/ Dale J. Aschemann  
Dale J. Aschemann, #6269347  
ASCHEMANN KELLER LLC  
300 North Monroe Street  
Marion, Illinois 62959-2326  
Telephone: (618) 998-9988

Facsimile: (618) 993-2565  
E-Mail: DaleA@quitamlaw.org

*Attorney for Relator,  
John Stone*

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF ILLINOIS**

UNITED STATES OF AMERICA,	)	
<i>ex rel.</i> JOHN STONE, and the States of Illinois,	)	
California, Florida, Louisiana, Massachusetts,	)	
Michigan, Montana, Nevada, New Jersey,	)	
New Mexico, New York, Oklahoma,	)	
Rhode Island, Tennessee, Texas, Virginia	)	
and Wisconsin, ex re. JOHN STONE,	)	
	)	
Plaintiffs,	)	Honorable James B. Zagel
	)	
v.	)	Civil Action No: 1:09-cv-04319
	)	
OMNICARE, INC.,	)	Magistrate Morton Denlow
	)	
Defendant.	)	

**CERTIFICATE OF SERVICE**

I hereby certify that on the 15th day of September 2011, I electronically filed **Plaintiffs' First Amended Complaint** with the Clerk of Court using the CM/ECF system which will send notification of such filing(s) to the following:

**AUSA**  
USAILN.ECFAUSA@usdoj.gov

**Eric Alan Dubelier**  
edubelier@reedsmith.com

**Robin J Elowe**  
relowe@reedsmith.com, rpieper@reedsmith.com

**Steven Alan Miller**  
smiller@sachnoff.com, akufro@sachnoff.com

**Katherine Joanne Seikaly**  
kseikaly@reedsmith.com

\_\_\_\_\_  
/s/ Dale J. Aschemann  
Dale J. Aschemann, #6269347  
ASCHEMANN KELLER LLC  
300 North Monroe Street

Marion, Illinois 62959-2326  
Telephone: (618) 998-9988  
Facsimile: (618) 993-2565  
E-Mail: DaleA@quitamlaw.org

*Attorney for Relator,  
John Stone*